

WHAT IS CLAIMED IS:

1. A method of sterilizing a balloon susceptible to degradation by ionizing radiation, comprising
 - (a) packaging said balloon in a pouch capable of providing a barrier to atmospheric oxygen;
 - (b) exposing said balloon enclosed in said pouch to a nitrogen gas flush sufficient to reduce the oxygen content within said pouch to less than about 10%; and
 - (c) exposing said balloon enclosed in said pouch to ionizing radiation, wherein said ionizing radiation is either gamma radiation or electron beam radiation at a dose of no greater than about 100 kGy.
2. A method according to claim 1, wherein said balloon is part of a balloon dilatation catheter.
3. A method according to claims 1 or 2, wherein said balloon is manufactured from one or more block polymers selected from the group consisting of polyester block copolymers, polyamide block copolymers, polyurethane block copolymers, a mixture of nylon and polyamide block copolymers, and a mixture of polyethylene terephthalate and polyester block copolymers.
4. A method according to claims 1 or 2, wherein said pouch comprises:
 - (a) a first layer;
 - (b) a second layer; and
 - (c) a third layer.
5. A method according to claim 4, wherein said pouch comprises:
 - (a) a first layer comprising 12 μ PET, 25.4 μ WPE/Foil/Adhesive and 50 μ Clear EZ Peel[®] material;

- (b) a second layer comprising 2FS Uncoated Tyvek[®] material, porosity 18-240 seconds by the Gurley porosimeter test; and
 - (c) a third layer comprising 12 μ PET, 25.4 μ WPE/Foil/Adhesive and 50 μ Clear EZ Peel[®] material;
- wherein said second layer is between said first and third layers.

6. A method of claims 1 or 2, wherein said pouch further comprises an oxygen absorber.
7. A method according to claim 1, wherein said oxygen content is between about 5% and about 10%.
8. A method according to claim 1, wherein said oxygen content is less than about 1%.
9. A sterilized balloon prepared by a method according to claim 1.
10. A sterilized balloon catheter prepared by the method according to claim 2.
11. A method of sterilizing a balloon susceptible to degradation by ionizing radiation, comprising:
 - (a) packaging said balloon in a pouch capable of providing a barrier to atmospheric oxygen;
 - (b) exposing said balloon enclosed in said pouch to a nitrogen gas flush sufficient to reduce the oxygen content in said pouch; and
 - (c) exposing said balloon enclosed in said pouch to ionizing radiation, while avoiding the concomitant degradation associated with sterilization at atmospheric oxygen levels.
12. A method according to claim 11, wherein said balloon is part of a balloon dilatation catheter.

13. A method according to claims 11 or 12, wherein said balloon is manufactured from one or more block polymers selected from the group consisting of polyester block copolymers, polyamide block copolymers, polyurethane block copolymers, a mixture of nylon and polyamide block copolymers, and a mixture of polyethylene terephthalate and polyester block copolymers.

14. A method according to claims 11 or 12, wherein said pouch comprises:

- (a) a first layer;
- (b) a second layer; and
- (c) a third layer.

15. A method according to claim 14, wherein said pouch comprises:

- (a) a first layer comprising 12 μ PET, 25.4 μ WPE/Foil/Adhesive and 50 μ Clear EZ Peel[®] material;
- (b) a second layer comprising 2FS Uncoated Tyvek[®] material, porosity 18-240 seconds by the Gurley porosimeter test; and
- (c) a third layer comprising 12 μ PET, 25.4 μ WPE/Foil/Adhesive and 50 μ Clear EZ Peel[®] material;

wherein said second layer is between said first and third layers.

16. A method of claims 11 or 12, wherein said pouch further comprises an oxygen absorber.

17. A method according to claim 11, wherein said ionizing radiation is either gamma irradiation or electron beam irradiation.

18. A method according to claim 17, wherein said gamma irradiation is the administered at a dose rate of about 1 kGy/hrs to about 10 kGy/hrs.

19. A method according to claim 17, wherein said electron beam irradiation is administered at a dose rate of no greater than about 20 kGy/s.

20. A method according to claim 11, wherein said nitrogen gas flush is administered at a pressure of less than about 10 psi and said oxygen content is less than about 10%.

21. A method according to claim 20, wherein said oxygen content is between about 5% and about 10%.

22. A method according to claim 20, wherein said oxygen content is less than about 1%.

23. A sterilized balloon prepared by a method according to claim 11.

24. A sterilized balloon catheter prepared by the method according to claim 12.